

BLA 761156/S-012, S-014, S-015

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Pratik Dherange, MS
Associate Director, Regulatory Affairs
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Pratik Dherange:

Please refer to your supplemental biologics license applications (sBLAs) received May 6, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Sogroya (somapacitan-beco) injection.

These Prior Approval sBLAs provide for addition of the following new indications for the treatment of pediatric patients aged 2.5 years and older with:

- S-012: Short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age
- S-014: Growth failure associated with Noonan syndrome (NS)
- S-015: Idiopathic Short Stature (ISS)

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling, with minor editorial revisions listed below and reflected in the enclosed labeling.

- Revision dates in the Prescribing Information and Patient Package Insert were updated to reflect the date of approval of these supplements.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,¹ that is identical to the enclosed labeling (text for the Prescribing Information,

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Patient Package Insert, Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for

- ages 0 to <2.5 years for pediatric patients born small for gestational age,
- ages 0 to <2.5 years for pediatric patients with Noonan syndrome, and
- ages 0 to <2.5 years for pediatric patients with idiopathic short stature

because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group. For children born small for gestational age (SGA), initiation of growth hormone (GH) therapy is not recommended before 2 years of age as many of these children have appropriate catch-up growth by this time, and to allow for evaluation of underlying growth-limiting conditions if they do not have appropriate growth by this time. For children with idiopathic short stature (ISS), this is a diagnosis of exclusion and an appropriate duration of time to evaluate for growth failure and evaluation of underlying growth-limiting conditions must also be conducted; it is also unlikely that there will be a major benefit to treatment before the

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

age of 2.5 years. For children with Noonan syndrome (NS), treatment of short stature with GH therapy during early childhood, including < 2.5 years of age, is controversial, in part due to safety concerns such as cardiac comorbidity and increased risk of certain malignancies.

We note that you have fulfilled the pediatric study requirement for

- ages \geq 2.5 years for pediatric patients born small for gestational age,
- ages \geq 2.5 years for pediatric patients with Noonan syndrome, and
- ages \geq 2.5 years for pediatric patients with idiopathic short stature

for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

If you have any questions, contact Elisabeth Hanan, Chief, Project Management Staff, at 240-402-0350 or Elisabeth.Hanan@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Marina Zemskova, MD
Deputy Director
Division of General Endocrinology
Office of Cardiology, Hematology, Endocrinology,
and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - Instructions for Use
 - 5 mg, 10 mg (versions approved October 1, 2021)
 - 15 mg (version approved April 28, 2023)
 - FlexPro PenMate (version approved January 31, 2025)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARINA ZEMSKOVA
02/27/2026 02:52:00 PM